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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,321	12/04/2001	Stefan Brust	38137-0019	1464

26633 7590 10/10/2003

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/000,321	BRUST ET AL.	
	Examin r	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *01* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *24-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction Requirement

37 C.F.R. § 1.126

1. The numbering of claims is not in accordance with 37 C.F.R. § 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 C.F.R. § 1.121(b), they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). This application contained originally filed claims 1-23. The preliminary amendment submitted 04 December, 2001, canceled claims 1-27 without prejudice or disclaimer and introduced new claims 30-55. Accordingly, originally presented claims 1-23 have been canceled without prejudice or disclaimer and **misnumbered claims 30-55 have been renumbered 24-49, respectively.**

35 U.S.C. § 121

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

a. Group I, claim(s) 24-35, drawn to **human immunodeficiency virus type 1 (HIV-1) peptides**, classified in class 530, subclasses 300 and 324-326.

b. Group II, claim(s) 36-41, drawn to **methods and diagnostic kits for the detection of retroviral antibodies** employing a viral peptide, classified in class 435, subclass 7.1.

c. Group III, claim(s) 42 and 43, drawn to a **method for immunizing against retroviral infection** through the administration of a suitable composition, classified in class 424, subclasses 188.1 and 208.1.

d. Group IV, claim(s) 44, drawn to a **nucleic acid** encoding an HIV-1 peptide, classified in class 536, subclass 23.72.

e. Group V, claim(s) 45-49, drawn to **methods for the detection of HIV nucleic acids**, classified in class 435, subclass 6.

3. **Applicants are advised that if Group V is selected, a single HIV-1 or -2 gene (e.g., *gag*, *pol*, *env*, *vif*, *nef*) or regulatory element (e.g., LTR) should also be elected.** This is **NOT** a species election requirement, but rather a restriction requirement. Each of the regions detected in the claimed methodology is structurally and functionally unrelated. Different primers and amplification conditions will be required for each region amplified. Accordingly, amplification methods directed toward each individual gene or regulatory region are independent and distinct. Appropriate amendment of the claim language to reflect the restriction requirement will be necessary if this group is selected.

4. The inventions are distinct, each from the other because of the following reasons:

5. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the identified groups are directed toward structurally and functionally disparate chemical molecules (e.g., amino acids or nucleic acids) with different attendant physical and chemical properties. Accordingly, each group is clearly directed toward a different inventive entity.

6. Inventions II/III/V are all are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified methodologies is directed toward a different scientific objective (e.g.,

immunization, antibody detection, nucleic acid detection) that employs different reagents (e.g., peptides, vaccinating compositions, nucleotide sequence primers) and protocols. Accordingly, each of the identified groups is clearly directed toward a different inventive concept.

7. Inventions I and II/III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the peptides of Group I can be employed in a number of materially different processes such as antibody binding assays, receptor-ligand binding assays, antibody production, and viral inhibitory assays.

8. Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the peptides of Group I are neither required nor utilized by the methodology of Group V. Accordingly, each group is clearly directed toward a different invention.

9. Inventions IV and II/III/V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the nucleic acids of Group IV are neither required nor utilized by the methodologies of Groups II, III, and V. Accordingly, each group is clearly directed toward a novel inventive concept.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

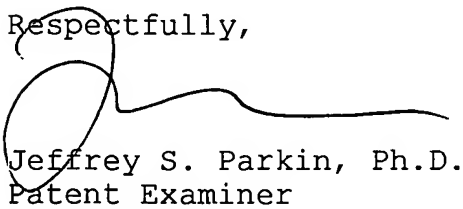
Correspondence

13. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

14. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following Group 1600 fax number: (703) 872-9306. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027,

respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

09 October, 2003